UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF LOUISIANA

IN RE: TAXOTERE (DOCETAXEL) PRODUCTS LIABILITY LITIGATION	)	**MDL No. 16-2740**
	)	**SECTION: "H" (5)**
This document relates to: Brenda Mixon, 18-6581	)	

ORDER AND REASONS

Before the Court a Motion for Summary Judgment on the Claims of Plaintiff Brenda Mixon and Entry of Order to Show Cause (Doc. 10978). The Court held oral argument on the Motion on November 17, 2020. For the following reasons, the Motion is **GRANTED.**

BACKGROUND

Plaintiffs in this multidistrict litigation ("MDL") are suing several pharmaceutical companies that manufactured and/or distributed a chemotherapy drug, Taxotere or docetaxel,[1] that Plaintiffs were administered for the treatment of breast cancer or other forms of cancer. Among these companies are Defendants sanofi-aventis U.S. LLC and Sanofi U.S. Services Inc. (collectively, "Sanofi" or "Defendants"). Plaintiffs allege that the drug caused permanent alopecia—in other words, permanent hair loss. Plaintiffs bring claims of failure to warn, negligent misrepresentation, fraudulent misrepresentation, and more. The first bellwether trial was held in September 2019, and the second trial is set for 2021.[2]

In the instant Motion, Sanofi moves for summary judgment against Plaintiff Brenda Mixon. Sanofi argues that the Michigan Products Liability Act

[1] Docetaxel is the generic version of Taxotere.
[2] The second trial was continued due to the COVID-19 pandemic.

("MPLA") bars Plaintiff's claims. Sanofi further moves the Court to enter an order requiring similarly situated MDL Plaintiffs—Plaintiffs who were prescribed or administered Taxotere in Michigan—to show cause why the MPLA does not also bar their claims. Plaintiff Mixon opposes Sanofi's Motion.

LEGAL STANDARD

Summary judgment is warranted where "there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law."[3] A genuine issue of fact exists only "if the evidence is such that a reasonable jury could return a verdict for the nonmoving party."[4] Federal Rule of Civil Procedure 56 "mandates the entry of summary judgment, after adequate time for discovery and upon motion, against a party who fails to make a showing sufficient to establish the existence of an element essential to that party's case, and on which that party will bear the burden of proof at trial."[5]

LAW AND ANALYSIS

The parties agree that Michigan law governs this suit. Sanofi argues that Subsection 5 of the MPLA provides a complete defense to liability here. Subsection 5 provides as follows:

> In a product liability action against a manufacturer or seller, a product that is a drug is not defective or unreasonably dangerous, and the manufacturer or seller is not liable, if the drug was approved for safety and efficacy by the United States food and drug administration, and the drug and its labeling were in compliance with the United States food and drug

[3] FED. R. CIV. P. 56.
[4] Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 248 (1986).
[5] Celotex Corp. v. Catrett, 477 U.S. 317, 322 (1986).

> administration's approval at the time the drug left the control of the manufacturer or seller.[6]

Sanofi avers that consistent with this statute, Taxotere was (1) approved for safety and efficacy by the FDA, and (2) the drug and its labeling were in compliance with FDA approval at the time the drug left Sanofi's control.

In response, Plaintiff does not dispute this, but Plaintiff invokes an exception under Subsection 5. The exception provides as follows:

> This subsection does not apply if the defendant at any time before the event that allegedly caused the injury does any of the following:
>
> (a) Intentionally withholds from or misrepresents to the United States food and drug administration information concerning the drug that is required to be submitted under the federal food, drug, and cosmetic act . . . and the drug would not have been approved, or the United States food and drug administration would have withdrawn approval for the drug if the information were accurately submitted.[7]

Plaintiff, however, acknowledges that certain courts, including the Sixth Circuit, have held that this exception is preempted by the Federal Food, Drug, and Cosmetic Act ("FDCA"), as amended by the Medical Device Amendments of 1976 ("MDA"). Plaintiff notes that a Fifth Circuit decision, *Lofton v. McNeil Consumer & Specialty Pharmaceuticals*, [8] also supports a finding of preemption. Plaintiff argues that if this Court agrees that the exception is preempted, the Court should find that Subsection 5 is preempted in its entirety and that Sanofi's defense falls with it.

This Court finds that the exception at issue is preempted. This preemption stems from the Supreme Court's decision in *Buckman Company v.*

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[6] MICH. COMP. LAWS ANN. § 600.2946(5).
[7] *Id.*
[8] 672 F.3d 372, 380 (5th Cir. 2012).

Plaintiff's Legal Committee.[9] In *Buckman*, thousands of patients alleged that they were injured from the use of orthopedic bone screws in their spines.[10] The patients sued a consulting company that had helped the manufacturer of the bone screws navigate the federal regulatory process.[11] The patients alleged that the consulting company and the manufacturer made fraudulent representations to the FDA in the course of obtaining approval to market the screws.[12]

The Supreme Court held that the patients' state law "fraud-on-the-FDA" claims were preempted under the FDCA, as amended by the MDA.[13] The Court began its analysis by noting that "[p]olicing fraud against federal agencies is hardly 'a field which the States have traditionally occupied,' . . . such as to warrant a presumption against finding federal pre-emption of a state-law cause of action."[14] Under this framework, the Court held that the patients' state law fraud-on-the-FDA claims conflicted with federal law.[15] The Court explained as follows:

> The conflict stems from the fact that the federal statutory scheme amply empowers the FDA to punish and deter fraud against the Administration, and that this authority is used by the Administration to achieve a somewhat delicate balance of statutory objectives. The balance sought by the Administration can be skewed by allowing fraud-on-the-FDA claims under state tort law.[16]

The Court further explained that if states could simultaneously police fraud on the FDA, manufacturers may be discouraged from pursuing FDA approval for

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[9] 531 U.S. 341 (2001).
[10] *Id.* at 343, 346.
[11] *Id.* at 343.
[12] *Id.*
[13] *Id.*
[14] *Id.* at 347.
[15] *Id.* at 348.
[16] *Id.*

potentially beneficial medical advances for fear that they may be exposed to unpredictable civil liability.[17] Applicants would also fear that while their disclosures were sufficient for the FDA, they may later be deemed insufficient in state court.[18] "Applicants would then have an incentive to submit a deluge of information that the Administration neither wants nor needs, resulting in additional burdens on the FDA's evaluation of an application."[19] Ultimately, noting that "this sort of litigation would exert an extraneous pull on the scheme established by Congress," the Supreme Court held that the patients' claims were impliedly preempted.[20]

Following *Buckman*, the Sixth Circuit, in *Garcia v. Wyeth–Ayerst Laboratories*, held that "suits against drug manufacturers under Michigan law in which the plaintiff seeks to defeat immunity by invoking the [MPLA's] fraud exceptions are equivalent to fraud-on-the-FDA claims and are thus preempted."[21] Notably, the Sixth Circuit recognized that in cases where the FDA itself has determined that the manufacturer committed fraud, the MPLA's exception would not be preempted.[22] In *Lofton*, the Fifth Circuit faced a Texas law similar to the MPLA, protecting a manufacturer that complied with the FDA except in cases where the manufacturer withheld information from the FDA.[23] After discussing *Garcia*, the Fifth Circuit ruled that unless the FDA itself finds fraud, "the threat of imposing state liability on a drug manufacturer for defrauding the FDA intrudes on the competency of the FDA

[17] *Id.* at 350.
[18] *Id.* at 351.
[19] *Id.*
[20] *Id.* at 353.
[21] Marsh v. Genentech, Inc., 693 F.3d 546, 551 (6th Cir. 2012) (citing Garcia v. Wyeth–Ayerst Laboratories, 385 F.3d 961, 965–66 (6th Cir. 2004)).
[22] *See id.* at 550 n.3.
[23] *Lofton*, 672 F.3d at 374.

and its relationship with regulated entities."[24] Thus, the Fifth Circuit found the Texas fraud-on-the-FDA exception preempted.[25]

Plaintiff Brenda Mixon does not allege that the FDA itself has found fraud in this case. This Court, then, like the *Garcia* and *Lofton* courts, adopts the reasoning of *Buckman* and finds that the MPLA fraud-on-the-FDA exception is preempted here. This Court further finds that the exception is severable, rejecting Plaintiff's argument that Subsection 5 is preempted in its entirety. As the Sixth Circuit explained in *Garcia*, the Michigan Legislature has provided a general severability clause:

> If any portion of an act or the application thereof to any person or circumstances shall be found to be invalid by a court, such invalidity shall not affect the remaining portions or applications of the act which can be given effect without the invalid portion or application . . . , and to this end acts are declared to be severable.[26]

The *Garcia* court further explained that severing the exception and upholding Subsection 5 appeared consistent with the intent of the Michigan Legislature behind the MPLA.[27] Plaintiff Mixon has not convinced this Court otherwise.

In an additional argument, Plaintiff Mixon asserts that the MPLA violates her Equal Protection rights under the Michigan Constitution. She

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[24] *Id*. at 380.
[25] *Id*.
[26] *Garcia*, 385 F.3d at 966–67 (quoting MICH. COMP. LAWS § 8.5).
[27] The court reasoned as follows:

> We find that Plaintiff has failed to persuade us that the district court erred as a matter of law, and that given a choice between immunity absent a finding of bribery or fraud by the Federal Government and no immunity, the Michigan Legislature would prefer the former option. First, it appears that the Michigan legislature was concerned that unlimited liability for drug manufacturers would threaten the financial viability of many enterprises and could add substantially to the cost and unavailability of many drugs. . . . Second, and most importantly, severing the preemption exemptions will not give license to drug manufacturers to use bribery or fraud as a means of

argues that due to the protection afforded to drug manufacturers under the MPLA, she is arbitrarily being denied access to justice—"justice that is available to residents of other states and to Michigan residents hurt by other products."[28] She avers that the MPLA irrationally distinguishes between FDA-approved drugs and other products.[29]

In *Garcia*, the Sixth Circuit rejected the notion that Subsection 5 of the MPLA is denying anyone access to the courts.[30] This Court again adopts *Garcia*'s reasoning and rejects Mixon's argument. This Court further finds that Mixon has failed to show that the Michigan Legislature lacked a rational basis for providing protection to drug manufacturers and sellers. Subsection 5 was prompted by "Michigan's interest in making prescription drugs more available to its residents."[31] Consistent with this, Subsection 5 protects drug companies from liability where they have complied with the FDA.

Lastly, this Court rejects Plaintiff's request to certify these questions to the Michigan Supreme Court. Plaintiff implies that this case deals with novel and unsettled questions of state law. This Court disagrees. In large part,

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> obtaining FDA approval, then rely on that approval as a shield from products liability: it will merely place responsibility for prosecuting bribery or fraud on the FDA in the hands of the Federal Government rather than state courts.

See id. at 967.

[28] Doc. 11324 at 17.

[29] *Id.*

[30] The *Garcia* court explained as follows:

> In this case, the plaintiff does not allege that she was unable to gain access to court to litigate her claim. Rather, she contends in essence that Section 600.2946(5) requires too much, and that the immunity it grants to drug manufacturers is too broad. These allegations do not constitute a claim of denial of access to the courts.

Garcia, 385 F.3d at 968.

[31] Rowe v. Hoffman-La Roche, Inc., 917 A.2d 767, 774 (N.J. 2007).

Sanofi's Motion involves straightforward issues on which other courts, including the Sixth Circuit, have plainly ruled.

CONCLUSION

Accordingly, for the foregoing reasons, the Motion for Summary Judgment on the Claims of Plaintiff Brenda Mixon and Entry of Order to Show Cause (Doc. 10978) is **GRANTED**.

IT IS FURTHER ORDERED that the parties jointly propose a show cause procedure to the Court, so the Court may consider whether the MPLA similarly bars the claims of other MDL Plaintiffs who were prescribed or administered Taxotere in Michigan.

New Orleans, Louisiana, this 7th day of April, 2021.

JANE TRICHE MILAZZO
UNITED STATES DISTRICT JUDGE